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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/516,662 | 03/13/2006 | Susan C. Bock | 21101.0021U2 | 2888 |

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| EXAMINER | |
|---|---|
| CARLSON, KAREN C | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/516,662 | BOCK ET AL. | |
| | Examiner | Art Unit | |
| | Karen Cochrane Carlson, Ph.D. | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2,3,10,11,29,30,33,39-41,43,51,61-63,65-67 and 71-74* is/are pending in the application.

4a) Of the above claim(s) *3,10,11,67,73 and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,29,30,33,39-41,43,51,61-63,65,66,71 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05,10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group 1, Claims 2, 29, 30, 33, 39-41, 43, 51, 61-63, 65, 66, 71, and 72 drawn to ATIII having a P3 substitution in the reply filed on September 17, 2007 is acknowledged. The traversal is on the ground(s) that all claims are drawn to a single inventive concept, that being substitutions within ATIII. This is not found persuasive because the substitutions are not overlapping and change the structure of ATIII. The search of one substitution does not encompass the search of all substitutions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 12-28, 31, 32, 34-38, 42, 44-50, 52-60, 64, 68-70 have been cancelled. The Examiner has withdrawn Claims 3, 10, 11, 67, 73, and 74 from further consideration because these Claims are drawn to non-elected inventions. Claims 2, 29, 30, 33, 39-41, 43, 51, 61-63, 65, 66, 71, and 72 are currently under examination.

Benefit of priority is to May 31, 2002.

Claim 40 objected to because of the following informalities: "nuetrophil" should be spelled --- neutrophil ---. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61-63 lack an outcome, that is, there is no statement that the administration of ATII variants will alleviate coagulation, for example.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 29, 30, 33, 39-41, 43, 51, 61-63, 65, 66, 71, and 72 are rejected on the ground of nonstatutory double patenting over at least claims 3, 15, 16, and 21-25, for example of U. S. Patent No. 6,878,813 (Bock et al.) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claims of the patent encompass mutations in ATIII at P3, and the instant application does not exclude mutations other than at P3.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2, 29, 30, 33, 39-41, 43, 51, 61-63, 66, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Bock et al. (USP 6,878,813, issued April 12, 2005 and having priority to May 12, 1998).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bock et al. teach ATIII Ala P3 substitution (Formula F (col 4)) to Ile (I), Ser (S), Gly(G), or Asp (D). At Table 2 and pages 42-43, the specification states that conservative amino acid substitutions are encompassed by the specific amino acid substitutions. Therefore, **Claim 2,**

wherein ATIII substitution at P3, is anticipated by the Asp (D) substitution, and wherein P3 is Leu is anticipated by Bock et al.'s Gly (G) and Ile (I) substitutions. **Claims 29, 30, 33, 39-41, 43, 51** are included in this rejection because these Claims further describe the activity inherent to this P3 substitution. See also Table 3 at Col 31-32.

At Col. 27, para. 1, E. coli was transformed with nucleic acid encoding the ATIII P3 mutations. Therefore, **Claim 66** is anticipated by Bock et al.

At Col. 5, line 41 and Col. 18, line 25, Bock et al. teach to use the P3 substituted ATIII proteins for the treatment of sepsis (**Claims 61-63, 72**).

Claims 2, 29, 30, 33, 39-41, 43, 51, 61-63, 66, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Dijkema et al. (WO 91/00291, published January 10, 1991).

Dijkema et al. teach variant ATIII having Ala291Asp. See page 2, Claim 2, and Fig 3 of Dijkema et al. Amino acid position 391 is P3. The nucleic acid encoding the variant ATIII was placed into COS cells and expressed.

Therefore, Dijkema et al. teach a variant of ATIII comprising a substitution at position P3 that is Asp (D) (**Claim 2**). **Claims 29, 30, 33, 39-41, 43, 51** are included in this rejection because these Claims further describe the activity inherent to this P3 substitution. Dijkema et al. expressed the nucleic acid encoding this ATIII variant in COS cells (**Claim 66**). At page 3, para. 4, Dijkema et al. teach that the ATIII variant is useful for treatment of septic shock (**Claims 61-63, 72**).

Claims 2, 29, 30, 33, 39-41, 43, 51, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Theunissen et al. (1993; J. Biol. Chem. 268(12): 9035-9040).

Theunissen et al. teach ATIII mutant having AlaP3Asp – see page 9037, left col, para. 1 and Figs 2 and 3). At page 9036, left col., ~2/3 down in para. 1. Theunissen et al. teach that the nucleic acid encoding this ATIII mutant was expressed in CHO cells.

Therefore, Theunissen et al. teach an ATIII mutant wherein P3 is Asp (D) (**Claim 2**). **Claims 29, 30, 33, 39-41, 43, 51** are included in this rejection because these Claims further describe the activity inherent to this P3 substitution. Theunissen et al. expressed the nucleic acid encoding this ATIII variant in CHO cells (**Claim 66**).

Note that Claim 65 is drawn to SEQ ID NO: 77. In SEQ ID NO: 77, the P3 position is Gln (Q).

| | | P3 | P2 | P1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ala | Leu | Glu | Ala | Gln | Gly | Arg | Ser | Leu | Asn | Pro | Asn | Arg | Val | Thr | Phe |
| 385 | | | | 390 | | | | | 395 | | | | | 400 | |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
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